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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

COLOMBIA

Communicated by the Government of Colombia

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

RESOLUTION NO. 6980 OF 28 MAY 1991, ESTABLISHING REGULATIONS FOR THE CONTROL OF THE IMPORT, EXPORT, MANUFACTURE, DISTRIBUTION AND SALE OF MEDICAMENTS, RAW MATERIALS AND PRECURSORS UNDER SPECIAL CONTROL

THE MINISTER OF HEALTH

in exercise of his legal powers, in particular those conferred upon him by chapter IV of Law 09 of 1979, Law 30 of 1986, and Regulatory Decree 3788 of 1986, and having heard the opinion of the Pharmaceutical Products Revision Commission,

RESOLVES:

CHAPTER I

DEFINITIONS

ARTICLE 1. The following definitions shall be adopted for the purposes of this Resolution:

(a) RAW MATERIAL OR SUBSTANCE UNDER SPECIAL CONTROL (DRUG UNDER SPECIAL CONTROL)

Is any pharmacologically active substance, whatever its origin, which produces immediate or non-immediate physical or mental dependence in human beings, which is such that, through the possibility of its abuse, may constitute some degree of risk when consumed, or which has been classified as such in the international agreements and accepted by the Pharmaceutical Products Revision Commission of the Ministry of Health.

(b) PRECURSOR OR PRECURSOR SUBSTANCE:

Is the substance or substances from which it is possible to synthesize, manufacture, process or obtain medicaments which produce physical or mental dependence.

(c) MEDICAMENTS UNDER SPECIAL CONTROL:

Are substances or mixtures of substances under special control which with or without further additions (excipients or vehicles) may be used for preparation of a definite pharmaceutical form.

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CHAPTER II

LIST OF RAW MATERIALS AND MEDICAMENTS UNDER SPECIAL CONTROL

ARTICLE 2. This shall cover each and every one of the substances and medicaments prepared with the raw materials that are included in the schedules of the so-called "NARCOTIC DRUGS UNDER INTERNATIONAL CONTROL".

PARAGRAPH 1. The health certificate which is granted for the sale of a medicament containing any of the above substances shall require authentication of its inclusion in the schedule of the International Narcotics Control Board, provided by the National Narcotics Fund of the Ministry of Health, which shall be appended to the relevant file and attested to in the decision to grant it.

GROUP I

PART I - NARCOTIC DRUGS AND SPECIAL ANALGESICS

A. Narcotic drugs and/or narcotic analgesics

1. Narcotic drugs included in Schedule I of the 1961 Convention and in Group I of the 1931 Convention or in one of them. 1/

Acetylmethadol
Acetyl-alpha-methylfentanyl
Acetorphine
Alphacetylmethadol
Alphameprodine
Alphamethadol
Alphamethylfentanyl
Alphaprodine
Alfentanyl
Allylprodine
Anileridine
Bezitramide
Benzethidine
Benzylmorphine
Betacetylmethadol
Beta-hydroxyfentanyl
Beta-hydroxy-3-methylfentanyl
Betameprodine
Betamethadol
Betaprodine
Cannabis (Indian hemp) and its resin (Cannabis resin)
Ketobemidone
Clonitazene
Coca (leaves)
Cocaine (methylester of benzoylecgonine)
Codoxime
Poppy straw concentrate (the material obtained when poppy straw has undergone a process to concentrate its alkaloids at the moment when being prepared for commerce)
Desomorphine
Dextromoramide
Diampromide
Diethylthiambutene
Diphenoxylate
Difenoxin
Dihydromorphine
Dimepheptanol
Dimenoxadol
Dimethylthiambutene
Dipipanone
Drotebanol
Ecgonine, its esters and derivatives which may be convertible into ecgonine and cocaine
Ethylmethylthiambutene
Etonitazene
Etorphine

1/ Note by the Secretariat: The text gives the chemical denomination of the substances appearing in the schedules. These denominations are the same as those in the international conventions on narcotics control and have therefore not been reproduced.

PARAGRAPH 2.

Etoxeridine
Phenadoxone
Phenampromide
Phenazocine
Phenomorphan
Phenoperidine
Fentanyl
Furethidine
Heroin
Hydrocodone
Hydromorphinol
Hydromorphone
Hydroxypethidine
Isomethadone
Levophenacylmorphan
Levomethorphan*
Levomoramide
Levorphanol*
Methadone
Methadone intermediate
Methazocine
Methyldihydromorphine
3-methylfentanyl
3-methylthiofentanyl
Metopon
Myrophine
Moramide intermediate
Morpheridine

PARAGRAPH 3.

Morphine**
Morphine bromomethylate and other morphine derivatives with pentavalent nitrogen including, in particular, morphine-N-oxide, one of which is codeine-N-oxide.
MPPP
Nicomorphine
Noracymethadol
Norlevorphanol
Normethadone
Normorphine
Norpipanone
Morphine-N-oxide
Opium**
Oxycodone
Oxymorphone
Para-fluorofentanyl
PEPAP
Pethidine
Pethidine, intermediate A
Pethidine, intermediate B
Pethidine, intermediate C
Piminodine
Piritramide
Proheptazine
Properidine
Racemethorphan
Racemoramide
Racemorphan
Sufentanyl
Thebacon
Thebaine

PARAGRAPH 4.

Tilidine
Thiofentanyl
Trimeperidine.

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* Dextromethorphan and dextrorphan are specifically excluded from this Schedule.

** Under the 1961 Convention, for the purpose of estimates and statistics, all products made directly from opium have to be considered as opium (preparations). When the preparations are not made directly from opium, but are obtained by mixing opium alkaloids (as happens, for example, in the case of pantopon, omnopon and papaveretum) the shall be considered as "morphine" preparations.

PARAGRAPH 5. The isomers, unless specifically excepted, of the drugs in this Schedule wherever the existence of such isomers is possible within the specific chemical designation.

PARAGRAPH 6. The esters and ethers of the drugs listed in the Schedule, unless appearing in another Schedule, whenever the existence of such esters or ethers is possible.

PARAGRAPH 7. The salts of the drugs listed in this Schedule, including the salts of the esters, ethers and isomers as provided above, whenever the existence of such salts is possible.

PARAGRAPH 8. For the prescription and formulation of the medicaments in this group there is need for the official prescription book (Annex 8) relating to this Resolution and the total quantity of the medicaments prescribed in this group shall be such as required for ten (10) calendar days.

8. Special analgesics (moderate narcotics)

Butorphanol
Buprenorphine
Nalbuphine
Pentazocine
Tramadol

PARAGRAPH 9. The narcotics included in Schedule II of the 1961 Convention and Group II of the 1934 Convention or in one of them.

Acetyldihydrocodeine
Codeine
Dextropropoxyphene
Dihydrocodeine
Ethylmorphine
Pholcodine
Nicocodine
Nicodicodine
Norcodeine
Propiram

PARAGRAPH 10. The isomers, unless specifically excepted, of the drugs in this Schedule, whenever the existence of such isomers is possible within the specific chemical designation.

PARAGRAPH 11. The salts of the drugs listed in this Schedule, including the salts of the isomers as provided above whenever the existence of such salts is possible.

PART II - PREPARATIONS FOR WHICH NO EXPORT LICENCE IS REQUIRED AND WHICH ARE INCLUDED IN SCHEDULE III OF THE 1961 CONVENTION

1. Preparations of:

Acetyldihydrocodeine
Codeine
Dihydrocodeine
Ethylmorphine
Nicocodine
Pholcodine
Nicodicodine and
Norcodeine

PARAGRAPH 12. When compounded with one or more ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent in undivided preparations.

2. Preparations of propiram containing not more than 100 milligrams of propiram per dosage unit and compounded with at least the same amount of methylcellulose.

3. Preparations for oral use containing not more than 135 milligrams of dextropropoxyphene per dosage unit or with a concentration of not more than 2.5 per cent in undivided preparations, so that these do not contain any substance that would be subject to control under the 1971 Convention on Psychotropic Substances.

4. Preparations of cocaine containing not more than 0.1 per cent of cocaine calculated as cocaine base and preparations of opium or morphine containing not more than 0.2 per cent of morphine calculated as anhydrous morphine base and compounded with one or more other ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

5. Preparations of difenoxin containing, per dosage unit, not more than 0.5 milligrams of difenoxin and a quantity of atropine sulphate equivalent to at least 5 per cent of the dose of difenoxin.

6. Preparations of diphenoxylate containing, per dosage unit, not more than 2.5 milligrams of diphenoxylate calculated as base and a quantity of atropine sulphate equivalent to at least 1 per cent of the dose of diphenoxylate.

7. Pulvis ipecacuanhae et opii compositus

10 per cent opium in powder
10 per cent ipecacuana root, well mixed with
80 per cent of any other powdered ingredient containing no drug.

8. Preparations conforming to any of the formulae listed in this Schedule and mixtures of such preparations with any material which contains no drug.

GROUP II

BARBITURATES OR MEDICAMENTS CONTAINING BARBITURATES

Each and every one of the substances derived from MALONYLUREA (barbituric acid) belong to the monopoly of the National Narcotics Fund.

No.	GENERIC NAME
1.	Allobarbital
2.	Amobarbital
3.	Barbital and its salts
4.	Butobarbital
5.	Butalbital
6.	Cyclobarbital
7.	Phenobarbital acid
8.	Phenobarbital sodium
9.	Methylphenobarbital
10.	Pentobarbital
11.	Secbutabarbital
12.	Secobarbital
13.	Vinylbital

GROUP III

AMPHETAMINES, ANOREXIANTS AND GENERAL STIMULANTS

No.	GENERIC NAME
1.	Amphetamine
2.	Amfepramone (diethyl propion)
3.	Benzphetamine
4.	Clobenzorex
5.	Clorfentermine
6.	Deanol
7.	Dexamphetamine
8.	Phendimetrazine
9.	Phenproporex
10.	Phentermine
11.	Levamphetamine
12.	Levomethamphetamine
13.	Mazindol
14.	Methamphetamine
15.	Methylphenidate

GROUP IV

NON-BARBITURATE TRANQUILLIZERS AND HYPNOTICS

No.	GENERIC NAME
1.	Adinazolam
2.	Alprazolam
3.	Bromazepam
4.	Bromophenone

GROUP IV (continued)

No.	GENERIC NAME	
5.	Brotizolam	
6.	Clobazam	
7.	Clonazepam	
8.	Clorazepat dipotassic	
9.	Chlordiazepoxide	
10.	Chloxazolam	
11.	Diazepam	
12.	Estazolam	
13.	Flunitrazepam	
14.	Flurazepam	
15.	Glutethimide	
16.	Halazepam	
17.	Chloral hydrate	
18.	Ketazolam	
19.	Lorazepam	
20.	Lormetazepam	
21.	Medazepam	
22.	Meprobamate	
23.	Methaqualone	(2)
24.	Mecloqualone	(2)
25.	Midazolam	
26.	Nitrazepam	
27.	Oxazepam	
28.	Oxazolam	
29.	Pyrovalerone	
30.	Prazepam	
31.	Temazepam	
32.	Tetrazepam	
33.	Triazolam	

PARAGRAPH 13. The numbers in brackets opposite the generic names in this article have the following meaning:

(1) Exclusive use of the National Narcotics Fund of the Ministry of Health.

(2) Use prohibited in Colombia.

PARAGRAPH 14. The medical prescription in the original plus one copy with the following information is required when dispensing and formulating the medicaments in this group.

(a) Doctor's name, address and telephone;

(b) Date;

(c) Name of the patient, address and identity card number;

(d) Name of the medicament, pharmaceutical form, total quantity in figures and daily dose;

(e) Signature of the doctor and his national registration number or the number under which he is registered with the relevant health service.

The total quantity prescribed for the medicaments in this group shall be as much as the dose required for thirty (30) calendar days.

GROUP V

OXYTOXICS AND UTERINE ANTIHAEMORRHAGICS

No.	GENERIC NAME
1.	Desaminocytoxine (demoxitocine)
2.	Ergonovin maleate
3.	Methylergonovin
4.	Oxytoxine
5.	Synthetic oxytoxine
6.	Prostaglandin E2
7.	Prostaglandin F2 alpha

ARTICLE 3. The raw materials and medicaments under special control in Group V shall come under this Resolution solely as concerns their distribution and sale.

ARTICLE 4. The following list of raw materials, precursors and medicaments under special control, in the same way as those envisaged in Article 2 of this Resolution, with the exception of those in Group V intended for import, shall be subject to the provisions of this Resolution.

GROUP VI

OTHER PSYCHOTROPIC SUBSTANCES

No.	GENERIC NAME
1.	Amitriptiline
2.	Amoxapine
3.	Bromoperidol
4.	Butriptiline
5.	Clorimipramine
6.	Clorlactam
7.	Clorpromazine
8.	Clozapine
9.	Dibencepine
10.	Doxepine
11.	Droperidol
12.	Etoperidone
13.	Flufenazine
14.	Flupentixol
15.	Haloperidol
16.	Imipramine
17.	Levomepromazine (Metotrimeprazine)
18.	Loxapine
19.	Maprotiline
20.	Mesoridazine
21.	Metapramine
22.	Mianserine
23.	Molindone
24.	Nomifensine
25.	Nortriptiline
26.	Opipramol
27.	Penfluridol
28.	Perfenazine
29.	Periciazine (Propericiazine)
30.	Pimozide
31.	Pipotiazine
32.	Pizotifeno
33.	Proclorperazine
34.	Protriptiline
35.	Quinupramine
36.	Sulpiride
37.	Sultopride
38.	Tiopropazato
39.	Tioproperazine
40.	Tioridazine
41.	Tiotixeno
42.	Tranilcipromine
43.	Trazodone
44.	Trifluoperazine (Fluopiran)
45.	Trifluoperidol
46.	Trifluopromazine
47.	Trimipramine
48.	Viloxazine

ARTICLE 5. In accordance with the international agreements and following an opinion by the Pharmaceutical Products Revision Commission, dealt with in Article 2 of Decree 981 of 1975, the Ministry of Health, or whoever acts on its behalf, shall determine the inclusion or exclusion of drugs, medicaments or precursors in the above lists.

PARAGRAPH. The Commission shall inform the National Narcotics Fund on the opinions it forms on pharmaceutical products under special control, within a period of not more than thirty (30) days.

The National Narcotics Fund shall abide by the same period for formulating and submitting any draft resolution envisaging the relevant changes.

ARTICLE 6. The Biochemical Products Monitoring Division, or whoever acts on its behalf, shall send the National Narcotics Fund immediately a copy of each health certificate that is granted for a medicament under special control and for those containing raw materials or precursors under special control.

CHAPTER III

REGISTRATION

ARTICLE 7. In order to import, export, process, synthesize and prepare medicaments under special control, the pharmaceutical laboratories and natural or legal persons shall register with the National Narcotics Fund of the Ministry of Health; for this purpose the legal representative and the technical director must submit:

1. A written request, attaching thereto an authentic photocopy of the national operating licence issued by the Ministry of Health;

2. A list of the drugs, raw materials and precursors, as well as the medicaments under special control that are to be manufactured, with the relevant photocopies of the health certificates;

3. A certificate indicating the establishment and legal representation of the applicant, issued by the competent authority when it involves a legal person. If it involves a natural or legal person acting as a trader, the mercantile register must be attached. The date of issue of this document may not be earlier than six (6) months before the request for registration.

ARTICLE 8. As soon as the documentation referred to in Article 7 has been received, the National Narcotics Fund of the Ministry of Health shall study the request within a period of seven (7) days and enter the registration in a book to be kept for the purpose.

By means of a decision giving grounds and issued by the Director of the National Narcotics Fund the applicant shall be notified of the registration, or, failing such, of the reasons why it was rejected.

The recourse of submission of the request to the Director of the National Narcotics Fund and an appeal to the Secretary-General against a decision to reject the registration shall be available.

ARTICLE 9. The registration dealt with in the above article shall be valid for five (5) years and be renewable for equal periods.

CHAPTER IV

IMPORT

ARTICLE 10. The pharmaceutical laboratories legally authorized are the only ones that may import raw materials, precursors or medicaments under special control, within the limits of the total estimates requested and authorized by the National Narcotics Fund, following a study of requirements on the basis of an examination to be made in each case.

ARTICLE 11. The legal representative or the technical director of the pharmaceutical laboratories importing the above-mentioned raw materials shall be obliged to submit the total estimates which they will have for the following year by 30 March of the immediately previous year at the latest (ANNEX 1, TABLE OF ESTIMATES OF NARCOTICS AND PSYCHOTROPICS).

ARTICLE 12. The import of drugs, raw materials, precursor substances and medicaments under special control dealt with in this Resolution shall be made only by the National Narcotics Fund of the Ministry of Health, or through the latter and in accordance with the following procedure:

1. It shall be duly registered by the National Narcotics Fund, as provided for in Article 7 of this Resolution;

2. There shall be an allotment for it within the annual estimate approved by the National Narcotics Fund;

3. The application shall be signed by the legal representative or attorney for each one of the imports that it is intended to carry out, indicating the:

   (a) Quantity of raw material, medicaments or precursor to be imported;

   (b) Generic name;

   (c) Medicaments or raw materials to be manufactured;

   (d) Number(s) of the Health Certificate(s);

   (e) Name of the supplier.

4. When the request has been received, the National Narcotics Fund of the Ministry of Health shall make the relevant study and within a maximum period of five (5) days shall inform the applicant of the number assigned to the request or, failing such, the reasons why the request is not accepted;

5. The original and two (2) photocopies of the import certificate shall be attached, completed in accordance with the instructions that the National Narcotics Fund of the Ministry of Health issues in that connection.

PARAGRAPH. The import certificate shall be processed by the National Narcotics Fund within a period of not more than five (5) days.

ARTICLE 13. Recognition of exemption from customs duty shall be subject to the procedure established by Decree 622 of 25 July 1990, or to that indicated in the other regulations which amend or supplement it.

PARAGRAPH. When dealing with substances subject to international control the relevant import certificate from the National Narcotics Fund shall be requested.

ARTICLE 14. When the merchandise arrives in the country, the party concerned shall notify the National Narcotics Fund to enable it to authorize the clearance of the waybill and to initiate the process for acceptance by national institutions.

ARTICLE 15. When the customs authorize the clearance or removal of the merchandise, the party concerned shall immediately advise the National Narcotics Fund of the Ministry of Health so that the latter may proceed accordingly; the relevant document for this procedure shall be made out and be signed by the authorized customs intermediary.

ARTICLE 16. The laboratory which will be using the raw material or imported medicament shall submit the following documents to the National Narcotics Fund of the Ministry of Health for the settlement of costs relating to the CIF value of the merchandise:

(a) Photocopy of the import licence;

(b) Photocopy of the invoice;

(c) Photocopy of the routing guide [guía de localización];

(d) Photocopy of the import declaration;

(e) Request for delivery signed by the manager, technical director or legal representative.

CHAPTER V

MANUFACTURE

ARTICLE 17. The pharmaceutical laboratories manufacturing medicaments under special control shall limit themselves to the following procedure:

(a) The sending of a request for delivery of the raw material to the National Narcotics Fund, signed by the technical director or legal representative;

(b) The acquisition of the raw material at or through the National Narcotics Fund of the Ministry of Health, following payment of the relevant dues, referred to in the article immediately above;

(c) The advising of the National Narcotics Fund and/or the Medicaments Control Office of the Sectional Health Service under its jurisdiction in writing of the date and hour of the processing ten calendar days in advance.

The processing shall always be attended by the technical director of the laboratory and may be carried out in the presence of an official from the National Narcotics Fund or Medicaments Control Office of the relevant Sectional Health Service.

The relevant document for the above procedure shall be made out in an original and two (2) copies and be signed and numbered (ANNEX 2, PROCESSING DOCUMENT).

The original of the document shall be sent to the National Narcotics Fund of the Ministry of Health or to the Sectional Health Service, as appropriate; one copy shall be placed in the laboratory files while the other shall be sent to the National Narcotics Fund when the processing is supervised by the relevant Sectional Health Service.

ARTICLE 18. The laboratories which use or process raw material or medicaments under special control acquired through the National Narcotics Fund of the Ministry of Health are obliged to keep:

(a) A movements ledger for the controlled raw materials, which shall have numbered pages and be registered with the National Narcotics Fund of the Ministry of Health and be inspected periodically by its officials;

(b) A file of the requests for professional samples made by the doctors and dentists, which the laboratory shall maintain for a period of two (2) years and be destroyed at their request.

PARAGRAPH. When raw materials under special control are used to make medicaments that are not under special control, the pharmaceutical laboratories shall be obliged to keep the ledger referred to in paragraph (a) of this article.

ARTICLE 19. The laboratories making medicaments under special control shall be obliged to send to the National Narcotics Fund, within the first ten (10) days of each month, a detailed report on the production and sale of medicaments under special control (ANNEX 3, TABLE SHOWING THE MOVEMENT OF COMPLETED PRODUCTS UNDER SPECIAL CONTROL).

ARTICLE 20. The pharmaceutical laboratories may not keep stocks of drugs, medicaments, raw materials or precursors under special control in quantities greater than authorized by the National Narcotics Fund of the Ministry of Health; the negotiations which in the event of force majeure are to be conducted between the laboratories regarding these substances shall require the approval of the Fund, following a written request signed by the vendor and purchaser, in which the relevant grounds are stated.

CHAPTER VI

DISTRIBUTION

ARTICLE 21. The following list of medicaments under special control shall be established, for which the preparation and distribution shall be carried out solely by the National Narcotics Fund of the Ministry of Health.

GENERIC NAME	PHARMACEUTICAL FORM
PHENOBARBITAL	Elixir - 0.4 per cent x 120 ml Ampoules - 200 mg x 1 ml Ampoules - 40 mg x 1 ml Tablets - 10 mg Tablets - 50 mg Tablets - 100 mg
HYDROMORPHONE	Ampoules - 2.0 mg x 1 ml Tablets - 2.5 mg
MORPHINE	Ampoules - 10 mg x 1 ml Solution - 3 per cent x 20 ml Drops - 2 per cent x 50 ml
MEPERIDINE (PETHIDINE)	Ampoules - 100 mg x 2 ml
ELIXIR OF PAREGORIC	Bottle - 120 ml.

PARAGRAPH. The other medicaments under special control not included in the list may be distributed directly by the manufacturing laboratories, even though the Narcotics Revolving Fund may later take charge of the distribution of all or some of them.

ARTICLE 22. The distribution and sale of medicaments under special control, dealt with in the article above, shall be made by the National Narcotics Fund of the Ministry of Health to the Sectional Revolving Funds, or from the latter to the legally authorized establishments under their jurisdiction and to natural persons only by medical prescription.

PARAGRAPH. The sale and delivery of medicaments under special control shall be made directly to the interested party, dispatch by mail being prohibited.

ARTICLE 23. For the purchase of medicaments under special control supplied by the National Narcotics Fund of the Ministry of Health, the Sectional Narcotics Revolving Funds shall submit their requests in writing with the approval of the relevant head of the Sectional Service or whoever acts for him.

ARTICLE 24. The National Narcotics Fund shall alone supply medicaments under special control to the:

1. Narcotics Revolving Funds of the relevant Sectional Health Services;

2. Units connected with or attached to the national health system of Bogotá and Cundinamarca, in which case the request shall be signed by the director of the unit.

ARTICLE 25. For the purchase of medicaments under special control distributed by the Sectional Narcotics Revolving Funds or those acting on their behalf, the pharmaceutical establishments legally authorized and the units associated with or attached to the national health system shall submit the request to the relevant Sectional Narcotics Revolving Fund, signed by the director or owner of the establishment or unit and the official in charge of it.

ARTICLE 26. The pharmaceutical laboratories which distribute medicaments under special control shall report in duplicate the sales in each department and per establishment, in accordance with Annex 4 (MONTHLY REPORT OF SALES AND MEDICAMENTS UNDER SPECIAL CONTROL OF LABORATORIES). This report shall be sent within the first ten (10) days of each month to the National Narcotics Fund of the Ministry of Health, which shall ensure the relevant distribution of it to the Sectional Narcotics Revolving Funds.

PARAGRAPH. In case of returns of medicaments under special control the laboratories shall report the total of such per product, their form and the pharmaceutical presentation.

For the destruction of these medicaments authorization shall be requested from the National Narcotics Fund of the Ministry of Health.

ARTICLE 27. The wholesalers legally authorized to distribute medicaments under special control shall send the relevant Sectional Narcotics Revolving Fund, within the first five (5) days of each month, a report in duplicate of the sales made of medicaments under special control to the retailers, in conformity with Annex 5 (MOVEMENT TABLE AND REPORT OF SALES OF MEDICAMENTS UNDER SPECIAL CONTROL TO WHOLESALERS).

ARTICLE 28. The pharmaceutical retailers legally authorized to handle and deal in medicaments under special control and the units associated with and attached to the National Health System shall send the Narcotics Revolving Fund of the relevant Sectional Health Service, within the first ten (10) days of each month, a monthly balance in duplicate showing the movement of these medicaments, supporting it with the original of each prescription dispensed, in accordance with Annex 6 (MONTHLY BALANCE OF SALES OF MEDICAMENTS UNDER SPECIAL CONTROL BY THE RETAILING ESTABLISHMENTS). A copy of this report shall be kept in the files of the establishment.

ARTICLE 29. Any pharmaceutical establishment legally authorized to sell medicaments under special control shall keep a ledger with numbered pages registered with the Narcotics Revolving Fund of the relevant Sectional Health Service, in which the movement of the products under special control is recorded.

ARTICLE 30. Any establishment legally authorized to manufacture, distribute, handle or sell medicaments under special control shall possess safe and adequate storage facilities, independently of the other medicaments.

ARTICLE 31. In case of removal or loss of medicaments under special control, the relevant report shall be submitted immediately to the competent authority and a copy of it sent to the Narcotics Revolving Fund of the relevant Sectional Service and to the National Narcotics Fund of the Ministry of Health, regardless of the action taken by the Sectional or National Revolving Fund.

ARTICLE 32. The Medicament Control Offices of the Sectional Health Services shall maintain updated lists of the establishments legally authorized to handle medicaments under special control and shall periodically send such lists and amendments to them to the National Narcotics Fund of the Ministry of Health.

CHAPTER VII

NARCOTICS REVOLVING FUNDS OF THE SECTIONAL HEALTH SERVICES

ARTICLE 33. The Medicament Control Offices of the Sectional Health Services shall be in charge of a pharmaceutical chemist legally practising his profession, in accordance with the provisions of Law 23 of 1962.

ARTICLE 34. With the entry into force of this Resolution, the Sectional Health Services shall organize or legally establish the Sectional Narcotics Revolving Funds, in accordance with the regulations which may be issued for that purpose by the National Narcotics Fund of the Ministry of Health.

ARTICLE 35. The Sectional Narcotics Revolving Funds shall have a special account for the management of their operations. Profits that accrue may only be used for improvements to the personnel and operation of the relevant Narcotics Revolving Fund and for supporting anti-drug dependence programmes that the Service under its jurisdiction implements.

ARTICLE 36. The Sectional Narcotics Revolving Funds, when reviewing the reports of the retail establishments, shall verify that the signatures and information in the prescriptions made out match the data recorded by the relevant professionals.

ARTICLE 37. The National Narcotics Fund of the Ministry of Health and the Sectional Narcotics Revolving Funds, whenever it is considered necessary, shall destroy the prescriptions referred to in Article 28 of this Resolution. Such action shall be recorded in the relevant document, a copy of which shall be sent to the National Narcotics Fund of the Ministry of Health.

ARTICLE 38. Within the first five (5) days of each month the Sectional Narcotics Revolving Funds shall send the National Narcotics Fund of the Ministry of Health a report in duplicate of the movement of medicaments under special control within their jurisdiction (ANNEX 7, MONTHLY REPORT OF MOVEMENTS OF THE SECTIONAL NARCOTICS REVOLVING FUNDS).

ARTICLE 39. Interdepartmental trading in medicaments under special control is prohibited.

ARTICLE 40. In order for a pharmaceutical establishment to deal in medicaments under special control it shall meet the following requirements:

(a) It must be legally registered with the relevant Sectional Health Service and there shall be in charge a pharmaceutical chemist, a pharmacy manager, a licensed pharmacist, a senior druggist or dispenser of drugs practising his profession, in accordance with the legal provisions in force.

(b) There must have been no previous record of sanctions against the owner or pharmacist in charge on account of mismanagement of medicaments under special control.

CHAPTER VIII

OFFICIAL PRESCRIPTION BOOK

ARTICLE 41. The Medicaments Control Offices of the Sectional Health Services shall adopt the official prescription book [recetario oficial] for prescribing and formulating the medicaments under special control featuring in Group I, Part A - NARCOTIC ANALGESICS, in conformity with the form in Annex 8 (OFFICIAL PRESCRIPTION BOOK).

ARTICLE 42. The official prescription book shall be supplied to professionals who are legally registered with the Sectional Health Service under the jurisdiction of which they are going to pursue the profession of doctor or dentist.

ARTICLE 43. The official prescription book shall be for personal use and not transferable, with the professional who receives it being responsible for its use.

ARTICLE 44. In order to acquire the official prescription book the professional shall:

(a) Submit a request in conformity with Annex 9 (REQUEST FOR THE SUPPLY OF THE OFFICIAL PRESCRIPTION BOOK);

(b) Accompany it with the counterfoils of the previous prescription book.

ARTICLE 45. When a professional loses the official prescription book, he shall immediately inform the Medicaments Control Office in writing, with an additional copy of the report. The Medicaments Control Office shall inform the retailing establishments so that they can refrain from dispensing prescriptions matching the numbers of the lost counterfoils.

CHAPTER IX

PROFESSIONAL DOCTORS AND DENTISTS

ARTICLE 46. Graduate doctors and dentists engaged in the legal exercise of their professions shall be obliged to register with the relevant Sectional Health Service and to make out their prescriptions in conformity with all the requirements of this Resolution.

ARTICLE 47. In exercise of their officially recognized duties in the provision of compulsory social service, doctors and dentists shall attach to the prescriptions for medicaments under special control the seal of the institution to which they are connected as well as their identity card number.

ARTICLE 48. Dentists with a university degree, in the legal exercise of their profession, may only prescribe the medicaments under special control contained in Schedules IB. Special Analgesics (Moderately Narcotic) and IV. Non-Barbiturate Tranquillizers and Hypnotics.

CHAPTER X

SALE AND CONSUMPTION

ARTICLE 49. The medicaments under special control shall only be dispensed following submission of the medical prescription in the original form and with a copy. Both the original and the copy shall record that it was dispensed; the original shall be filed by the establishment and the copy given to the party concerned.

ARTICLE 50. The medical prescription shall contain the following data:

(a) Name of the doctor, address and telephone;

(b) Date;

(c) Name of the patient, his address and the number of his identity card, if appropriate;

(d) Name of the medicament, pharmaceutical form, total quantity in figures and letters and the daily dose;

(e) Signature of the attending doctor and his national registration number or his registration number with the relevant health service.

ARTICLE 51. The total amount prescribed of the medicaments under special control shall take account of the following limits:

(a) Medicaments coming under Group IA "Narcotic Analgesics" up to the dose required for ten (10) calendar days;

(b) Medicaments coming under Group IB "Moderately Narcotic Analgesics", under Group II "Barbiturates or Medicaments containing Barbiturates, with the exception of Phenobarbital"; under Group III "Amphetamines and General Stimulants", and under Group IV "Non-Barbiturate Tranquillizers and Hypnotics", up to the dose required for thirty (30) calendar days;

(c) Medicaments coming under Group V "Oxytoxics and Uterine Antihaemorrhagics", with the prescribed dose being the responsibility of the attending doctor;

(d) Phenobarbital, up to the dose required for ninety (90) calendar days.

PARAGRAPH 1. When the prescription for medicaments under special control is made out for doses higher than the established ones, their sale shall require prior authorization by the National Narcotics Fund of the Ministry of Health or the relevant Sectional Narcotics Revolving Fund, which alone may authorize up to double the dose indicated in this article.

PARAGRAPH 2. In cases where the therapy is changed or the patient dies, should any of the medicaments supplied by the Narcotics Revolving Fund be left over, the person in charge of them shall return the products to the Fund, where the value of them will be reimbursed, if appropriate.

ARTICLE 52. Pharmaceutical establishments duly authorized shall be prohibited from dispensing prescriptions for medicaments under special control when more than fifteen (15) calendar days have passed since they were made out.

ARTICLE 53. Hospitals and health centres attached to the health system shall be obliged to issue the public with medicaments under special control.

ARTICLE 54. The distribution of clinical samples of medicaments under special control is prohibited.

ARTICLE 55. Pharmaceutical laboratories may provide professional doctors and dentists with medicaments under special control in the form of commercial samples when the latter request such in writing in the appropriate official prescription book and in a quantity equivalent to one authorized commercial unit.

CHAPTER XI

NATIONAL REGISTER OF DRUG DEPENDENTS

ARTICLE 56. The National Narcotics Fund of the Ministry of Health shall keep the National Register of Drug Dependents in connection with Group IA, which shall be confidential and enjoy the secrecy accorded by Law 57 of 1985, and the data in it shall be used only for the prevention of illicit drug trafficking and drug dependence.

ARTICLE 57. For the purposes of the National Register of Drug Dependents the National Narcotics Fund of the Ministry of Health shall provide the relevant Sectional Health Services or the individual concerned with a form to be filled in by the medical professionals who prescribe drugs or medicaments under special control for patients considered to be drug dependent.

Once the form has been completed by the attending doctor it shall be returned to the relevant Sectional Health Service.

PARAGRAPH 1. When the attending doctor does not have the form referred to in this article, he shall send the basic information on the treatment of drug dependents in his own prescription book to the relevant Sectional Health Service or whoever acts for it.

PARAGRAPH 2. When the attending doctor is a professional providing obligatory social service, the information referred to in this article shall be endorsed with the signature and seal of the director of the institution in which he offers his services.

ARTICLE 58. The form referred to in the above article shall contain as a minimum the following basic information:

(a) Name of the patient;

(b) Identification of the patient;

(c) Address and telephone number of the patient;

(d) Name of the medicament;

(e) Daily dose;

(f) Name of the attending doctor;

(g) Medical registration number;

(h) Address and telephone number of the attending doctor.

ARTICLE 59. The Narcotics Revolving Funds of the Sectional Health Services shall be obliged to adopt the Register of Drug Dependents under their jurisdiction.

PARAGRAPH. In the Sectional Health Services where no Sectional Narcotics Revolving Fund has been organized, the obligation referred to in this article shall apply to the Medicaments Control Office of the relevant Sectional Health Service or whoever acts for it while the Sectional Narcotics Revolving Fund is being organized.

ARTICLE 70. The National Narcotics Fund of the Ministry of Health and the Sectional Health Services or whoever acts for them shall be obliged to follow up the drug dependents and update the information relating to the register referred to in this Chapter.

The Sectional Health Services or whoever acts for them shall send the National Narcotics Fund the information contained in the register of drug dependents under their jurisdiction every three months.

CHAPTER XII

EXPORTS

ARTICLE 71. The export of drugs, medicaments, raw materials and precursors under special control shall be carried out in accordance with the international conventions on narcotic and psychotropic substances and following authorization by the National Narcotics Fund of the Ministry of Health.

ARTICLE 72. To obtain the authorization referred to in the article above the exporter shall meet the following requirements:

1. He shall be duly registered with the Narcotics Revolving Fund as provided for in article 7 of this Resolution;

2. The country to which the export will be made shall have an allotment for it in accordance with the international conventions;

3. The request shall be signed by the legal representative or attorney for each of the exports that it is intended to make, with indication of:

   (a) Quantity of raw material, medicament or precursor that is to be exported;

   (b) Generic name;

   (c) Number(s) of the health certificate(s), as appropriate;

   (d) Country of destination and name of the importer;

4. When it is a question of raw materials under special control, the original and two (2) photocopies of the export certificate shall be attached, in accordance with the regulations which are issued for such by the National Narcotics Fund;

5. When in accordance with the international agreements the importing country requires the export certificate, the exporter shall request it in writing from the Narcotics Revolving Fund, attaching the corresponding certificate from the importing country;

6. When the request has been received, the National Narcotics Fund of the Ministry of Health shall make the relevant study and within a maximum of five (5) days inform the individual concerned of the authorization number, or failing such, the reasons why the request has not been accepted.

PARAGRAPH. Once the export has been approved by the Colombian Institute of Foreign Trade (INCOMEX), or the unit representing it, the exporter shall request the National Narcotics Fund in writing, five (5) days in advance, for a visit by one of its officials to be present during the weighing and packaging of the raw material for export. This procedure shall be recorded in the corresponding document.

ARTICLE 73. The exporters shall be obliged to submit a six-monthly report on exports to the National Narcotics Fund, indicating:

(a) Generic name and commercial brand, if appropriate;

(b) Form, concentration and pharmaceutical presentation, if appropriate;

(c) Total quantity exported;

(d) Export certificate number;

(e) Country of destination.

CHAPTER XIII

HEALTH AND SAFETY MEASURES

ARTICLE 74. The health and safety measures contained in Law 09 of 1979 shall be applied against legally authorized pharmaceutical laboratories and establishments which perpetrate the mismanagement of substances and products under special control; the measures, which shall be imposed immediately, shall be of a preventive and transitory nature and shall be applied without prejudice to the sanctions that may have been applied under the provisions of Article 576 of that Law.

SANCTIONS

ARTICLE 75. Under the provisions of Article 577 of Law 09 of 1979, the following sanctions may be applied for failure to comply with the regulations envisaged here by the National Narcotics Fund or the delegated authority:

(a) Warning;

(b) Successive fines up to 10,000 minimum legal daily salaries at the maximum value in force at the time that the relevant ruling is made;

(c) Seizure of products or substances;

(d) Suspension or cancellation of the registration or licence;

(e) Temporary or permanent closure of the establishment.

PARAGRAPH. The sanctions envisaged here shall be strictly subject to the time-limits required and procedures envisaged in Decree 713 of 1984 and Decree 2092 of 1986, together with the other regulations which amend or supplement them.

ARTICLE 76. Fines will be imposed in the form of a ruling, stating the grounds, issued by the Director of the National Narcotics Fund of the Ministry of Health or by the Heads of the Sectional Health Services or whoever represents them.

ARTICLE 77. Fines shall be paid to the National Narcotics Fund of the Ministry of Health or to the Sectional Revolving Funds, as appropriate, within the first five (5) days following the final judgement imposing them.

Non-payment of the terms and quantities indicated may lead to closure of the establishment. The fine may be made payable by coercive jurisdiction.

PARAGRAPH. The sums collected by virtue of fines imposed for violation of this Resolution may be destined only for improvement of the documentation and operation of the relevant Narcotics Revolving Fund and for implementing programmes to combat drug dependence, as stipulated in Article 35 of this Resolution.

ARTICLE 78. The suspension of the operating licence and cancellation of the health registration shall be imposed by a decision and issued by the relevant authority, and stating the grounds.

ARTICLE 79. This Resolution shall take effect from the date of its publication and repeals any provisions which may run counter to it.

To be published, communicated and put into effect.

Done in Bogotá, on 28 May 1991

[Signed] _____
Camilo Gonzales Posso
Minister of Health

[Signed] _____
Sara Ines Gaviria Arias
Secretary-General